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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/656,422	09/05/2003	James R. Skarda	P-11278.00	8544

27581 7590 01/30/2006

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EXAMINER	
TOY, ALEX B	

ART UNIT	PAPER NUMBER
3739	

DATE MAILED: 01/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

PTO-90C (Rev. 10/03)

88

Office Action Summary	Application No.	Applicant(s)
	10/656,422	SKARDA, JAMES R.
	Examiner	Art Unit
	Alex B. Toy	3739

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on 20 December 2005.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-51 is/are pending in the application.

4a) Of the above claim(s) 16,17,19,21,22,38,39,41,43,44 and 47-51 is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1,3,6,8-10,12-14,18,20,23-26,28-37,40,42,45 and 46 is/are rejected.

7)☒ Claim(s) 2,4,5,7,11,15 and 27 is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

This action is in response to applicant's amendment filed on December 20, 2005. The objection to the drawings is withdrawn in view of the canceled features from claims 20 and 42. The objections and 112, first paragraph rejections of claims 20 and 42 are withdrawn in view of the appropriate amendments. The 112, second paragraph rejections of claims 2, 5, and 11 are withdrawn in view of the appropriate amendment.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 3, 6, 9-10, 12-14, 18, 20, 23-26, 28, 31-36, 40, 42, and 45-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Swanson et al. (U.S. Pat. No. 5,846,239) in view of Qian (U.S. Pat. No. 5,047,028).

Regarding claim 1, Swanson et al. disclose an ablation catheter comprising:

an elongated catheter body 12 extending between a catheter body proximal end 14 and a catheter body distal end 16 (Fig. 1), the elongated catheter body including elongated electrical conductor 32 extending between the catheter body proximal end and the catheter body distal end (col. 6, ln. 20-24 and Figs. 1 and 4), a fluid port 36 positioned in proximity to the catheter body proximal end and a fluid delivery lumen 34 extending between the port and the catheter body distal end (col. 5, ln. 36-44 and Figs. 1 and 2); and

a virtual electrode assembly 20 terminating the catheter body distal end and including an inner electrode 30 electrically coupled to the elongated conductor 32 (col. 6, ln. 20-24 and Fig. 4), a non-conductive outer cap 22 fixed over the electrode and a fluid chamber formed between the inner electrode and the outer cap (col. 6, ln. 32-38 and Fig. 4);

wherein the outer cap includes a cap inner surface, a cap outer surface and a plurality of pores 44 extending between the cap inner surface and the cap outer surface (col. 6, ln. 36-39 and Fig. 4);

the inner electrode includes one or more spacers 54 protruding from the exterior surface of the inner catheter and contacting the cap inner surface to maintain the fluid chamber between the inner electrode and the outer cap (col. 5, ln. 56-64 and Fig. 5); and

when the inner electrode is energized, via the elongated conductor, and a conductive fluid 38 is delivered by the fluid delivery lumen of the catheter, the

conductive fluid fills the fluid chamber and flows out from the chamber through the plurality of pores of the cap establishing ionic transport of ablation energy from the inner electrode to a target site in close proximity to the cap (col. 6, ln. 32-44 and Fig. 4).

The amendment invokes the means-plus-function language of 35 U.S.C. 112, 6th paragraph in claiming a means for coupling. Therefore, claim 1 is interpreted to include any structures equivalent to the one or more detents on the outer cap engaging the one or more spacers of the inner electrode that are described in the specification for performing the function claimed. See *In re Donaldson*, 16 F.3d 1189, 1193, 29 USPQ2d 1845, 1848 (Fed. Cir. 1994). Thus, the distal end of sheath 28 of Swanson is an equivalent structure for coupling the outer cap to the electrode assembly by engaging the one or more spacers of the inner electrode (Fig. 5).

The claim differs from Swanson et al. in calling for the inner electrode to include an interior fluid trunk in fluid communication with the fluid delivery lumen of the catheter body and to include one or more fluid distribution branches extending from the fluid trunk to the exterior surface so that the fluid is delivered through the one or more fluid distribution branches from the fluid trunk.

Qian, however, teaches a virtual electrode assembly comprising inner electrode 16 with an interior fluid trunk 10 in fluid communication with the fluid delivery lumen of the catheter body and one or more fluid distribution branches 14 extending from the fluid trunk to the exterior surface so that the fluid is delivered to the chamber through the one or more fluid distribution branches from the fluid trunk (col. 2, ln. 3-18 and Fig. 1).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have delivered the fluid in Swanson using an interior fluid trunk and distribution branches in view of the teaching of Qian because it is an obvious alternate structure for delivering fluid to facilitate ablation that is known in the art.

Regarding claim 3, Swanson et al. disclose the ablation catheter of claim 1 in view of Qian. In addition, Swanson et al. disclose the ablation catheter, wherein the outer cap 22 further includes a dome-shaped distal end region (Fig. 4).

Regarding claim 6, Swanson et al. disclose the ablation catheter of claim 1 in view of Qian. In addition, Swanson et al. disclose the ablation catheter, wherein the outer cap 22 is formed of a material comprising a rigid plastic (col. 6, ln. 37-38)..

Regarding claim 9, Swanson et al. disclose the ablation catheter of claim 1 in view of Qian. In addition, Swanson et al. disclose the ablation catheter, wherein the outer cap 22 is formed of a material comprising a rigid plastic (col. 6, ln. 37-38). The claim differs from Swanson et al. in calling for the outer cap to be formed of a material comprising an epoxy resin. It would have been obvious matter of design choice, however, to one of ordinary skill in the art at the time of the invention to have made the outer cap of Swanson et al. to be formed of a material comprising an epoxy resin because applicant has not disclosed that forming the outer cap from an epoxy resin material has any unique criticality or provides an advantage, is used for a particular purpose, or solves a stated problem that is not achieved by a similar material. One of ordinary skill in the art, furthermore, would have expected applicant's invention to

perform equally well with either the thermoplastic/elastomeric material taught by Swanson et al. or the claimed epoxy resin material because both are capable of performing the same functions of being biocompatible and resistant to the high temperatures associated with RF ablation as described in paragraph 16 of the applicant's specification.

Regarding claim 10, Swanson et al. disclose the ablation catheter of claim 1 in view of Qian. In addition, Swanson et al. disclose the ablation catheter, wherein the plurality of pores 44 are arrayed longitudinally along a length of the outer cap and circumferentially 360 degrees around the outer cap (Fig. 2).

Regarding claim 12, Swanson et al. disclose the ablation catheter of claim 1 in view of Qian. In addition, Swanson et al. disclose the ablation catheter, wherein a maximum diameter of each of the plurality of pores is sized to prevent ingress of blood cells into the fluid chamber from the cap outer surface (col. 8, ln. 1-6).

Regarding claim 13, Swanson et al. disclose the ablation catheter of claim 1 in view of Qian. In addition, Swanson et al. disclose the ablation catheter, wherein a maximum diameter of each of the plurality of pores is between approximately 0.0005 inch (12.7 μm) and 0.005 inch (127 μm) (col. 8, ln. 34-35).

Regarding claim 14, Swanson et al. disclose the ablation catheter of claim 1 in view of Qian. In addition, Swanson et al. disclose the ablation catheter, wherein the plurality of pores is formed by a process selected from the group consisting of laser drilling, chemical etching and sintering (col. 13, ln. 17-20).

It is also noted that claim 14 is a product-by-process claim. Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) and MPEP 2113.

Regarding claim 18, Swanson et al. disclose the ablation catheter of claim 1 in view of Qian. In addition, Swanson et al. disclose the ablation catheter, wherein the one or more spacers 54 extend circumferentially about a proximal end of the electrode (Fig. 5).

Regarding claim 20, Swanson et al. disclose the ablation catheter of claim 1 in view of Qian. In addition, Qian discloses the ablation catheter, wherein one of the one or more fluid distribution branches 14 passes through a distal end of the electrode (Fig. 1).

Regarding claim 23, Swanson et al. disclose the ablation catheter of claim 1 in view of Qian. The claim differs from Swanson et al. in calling for the diameter of the fluid trunk of the electrode to be between approximately 0.005 inch and approximately 0.030 inch. It would have been an obvious matter of design choice, however, to make the diameter of the fluid trunk of the electrode to be between approximately 0.005 inch and approximately 0.030 inch, since such a modification would have involved a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art. *In re Rose*, 105 USPQ 237 (CCPA 1955).

In addition, applicant has not established any criticality for this claim limitation in stating that "the trunk and branch diameters may be varied according to various performance requirements requiring different distributions of fluid flow" on page 5, paragraph 17 of the specification.

Regarding claim 24, Swanson et al. disclose the ablation catheter of claim 1 in view of Qian. The claim differs from Swanson et al. in calling for a diameter of each of the one or more fluid distribution branches to be between approximately 0.005 inch and approximately 0.030 inch. It would have been an obvious matter of design choice, however, to make a diameter of each of the one or more fluid distribution branches to be between approximately 0.005 inch and approximately 0.030 inch, since such a modification would have involved a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art. *In re Rose*, 105 USPQ 237 (CCPA 1955).

In addition, applicant has not established any criticality for this claim limitation in stating that "the trunk and branch diameters may be varied according to various performance requirements requiring different distributions of fluid flow" on page 5, paragraph 17 of the specification.

Regarding claim 25, Swanson et al. disclose a virtual ablation electrode assembly, comprising:

a non-conductive outer cap 22 including a cap inner surface, a cap outer surface and a plurality of pores 44 extending between the cap inner surface and the cap outer surface (col. 6, ln. 32-38 and Fig. 4);

one or more spacers 54 protruding from the exterior surface of the inner catheter and contacting the cap inner surface (col. 5, ln. 56-64 and Fig. 5); and

a fluid chamber formed between the inner electrode and the outer cap and maintained by the one more spacers (Fig. 5);

wherein, when the electrode is energized and when fluid is delivered through the one or more fluid distribution branches from the trunk, the conductive fluid fills the fluid chamber and flows out from the chamber through the plurality of pores of the cap establishing ionic transport of ablation energy from the inner electrode to a target site in close proximity to the cap (col. 6, ln. 32-44 and Fig. 4).

The amendment invokes the means-plus-function language of 35 U.S.C. 112, 6th paragraph in claiming a means for coupling. Therefore, claim 1 is interpreted to include any structures equivalent to the one or more detents on the outer cap engaging the one or more spacers of the inner electrode that are described in the specification for performing the function claimed. See *In re Donaldson*, 16 F.3d 1189, 1193, 29 USPQ2d 1845, 1848 (Fed. Cir. 1994). Thus, the distal end of sheath 28 of Swanson is an equivalent structure for coupling the outer cap to the electrode assembly by engaging the one or more spacers of the inner electrode (Fig. 5).

The claim differs from Swanson et al. in calling for the inner electrode to include an interior fluid trunk and one or more fluid distribution branches extending from the fluid trunk to the exterior surface.

Qian, however, teaches a virtual electrode assembly comprising inner electrode 16 with an interior fluid trunk 10 and one or more fluid distribution branches 14 extending from the fluid trunk to the exterior surface (col. 2, ln. 3-18 and Fig. 1).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have delivered the fluid in Swanson using an interior fluid trunk and distribution branches in view of the teaching of Qian because it is an obvious alternate structure for delivering fluid to facilitate ablation that is known in the art.

Regarding claim 26, Swanson et al. disclose the virtual ablation electrode of claim 25 in view of Qian. In addition, Swanson et al. disclose the ablation catheter, wherein the outer cap 22 further includes a dome-shaped distal end region (Fig. 4).

Regarding claim 28, Swanson et al. disclose the virtual ablation electrode of claim 25 in view of Qian. In addition, Swanson et al. disclose the ablation catheter, wherein the outer cap 22 is formed of a material comprising a rigid plastic (col. 6, ln. 37-38).

Regarding claim 31, Swanson et al. disclose the virtual ablation electrode of claim 25 in view of Qian. In addition, Swanson et al. disclose the ablation catheter, wherein the outer cap 22 is formed of a material comprising a rigid plastic (col. 6, ln. 37-38). The claim differs from Swanson et al. in calling for the outer cap to be formed of a material comprising an epoxy resin. It would have been obvious matter of design choice, however, to one of ordinary skill in the art at the time of the invention to have made the outer cap of Swanson et al. to be formed of a material comprising an epoxy

resin because applicant has not disclosed that forming the outer cap from an epoxy resin material has any unique criticality or provides an advantage, is used for a particular purpose, or solves a stated problem that is not achieved by a similar material. One of ordinary skill in the art, furthermore, would have expected applicant's invention to perform equally well with either the thermoplastic/elastomeric material taught by Swanson et al. or the claimed epoxy resin material because both are capable of performing the same functions of being biocompatible and resistant to the high temperatures associated with RF ablation as described in paragraph 16 of the applicant's specification.

Regarding claim 32, Swanson et al. disclose the virtual ablation electrode of claim 25 in view of Qian. In addition, Swanson et al. disclose the ablation catheter, wherein the plurality of pores 44 are arrayed longitudinally along a length of the outer cap and circumferentially 360 degrees around the outer cap (Fig. 2).

Regarding claim 33, Swanson et al. disclose the virtual ablation electrode of claims 25 and 26 in view of Qian. In addition, Swanson et al. disclose the ablation catheter, wherein the plurality of pores 44 are arrayed longitudinally along a length of the outer cap and circumferentially 360 degrees around the outer cap extending over the dome-shaped distal end region (Fig. 2).

Regarding claim 34, Swanson et al. disclose the virtual ablation electrode of claim 25 in view of Qian. In addition, Swanson et al. disclose the ablation catheter, wherein a maximum diameter of each of the plurality of pores is sized to prevent ingress of blood cells into the fluid chamber from the cap outer surface (col. 8, ln. 1-6).

Regarding claim 35, Swanson et al. disclose the virtual ablation electrode of claim 25 in view of Qian. In addition, Swanson et al. disclose the ablation catheter, wherein a maximum diameter of each of the plurality of pores is between approximately 0.0005 inch (12.7 μm) and 0.005 inch (127 μm) (col. 8, ln. 34-35).

Regarding claim 36, Swanson et al. disclose the ablation catheter of claim 25 in view of Qian. In addition, Swanson et al. disclose the ablation catheter, wherein the plurality of pores is formed by a process selected from the group consisting of laser drilling, chemical etching and sintering (col. 13, ln. 17-20).

It is also noted that claim 36 is a product-by-process claim. Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) and MPEP 2113.

Regarding claim 40, Swanson et al. disclose the virtual ablation electrode of claim 25 in view of Qian. In addition, Swanson et al. disclose the ablation catheter, wherein the one or more spacers 54 extend circumferentially about a proximal end of the electrode (Fig. 5).

Regarding claim 42, Swanson et al. disclose the virtual ablation electrode of claim 25 in view of Qian. In addition, Qian discloses the ablation catheter, wherein one

of the one or more fluid distribution branches 14 passes through a distal end of the electrode (Fig. 1).

Regarding claim 45, Swanson et al. disclose the virtual ablation electrode of claim 25 in view of Qian. The claim differs from Swanson et al. in calling for the diameter of the fluid trunk of the electrode to be between approximately 0.005 inch and approximately 0.030 inch. It would have been an obvious matter of design choice, however, to make the diameter of the fluid trunk of the electrode to be between approximately 0.005 inch and approximately 0.030 inch, since such a modification would have involved a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art. *In re Rose*, 105 USPQ 237 (CCPA 1955).

In addition, applicant has not established any criticality for this claim limitation in stating that "the trunk and branch diameters may be varied according to various performance requirements requiring different distributions of fluid flow" on page 5, paragraph 17 of the specification.

Regarding claim 46, Swanson et al. disclose the virtual ablation electrode of claim 25 in view of Qian. The claim differs from Swanson et al. in calling for a diameter of each of the one or more fluid distribution branches to be between approximately 0.005 inch and approximately 0.030 inch. It would have been an obvious matter of design choice, however, to make a diameter of each of the one or more fluid distribution branches to be between approximately 0.005 inch and approximately 0.030 inch, since such a modification would have involved a mere change in the size of a component. A

change in size is generally recognized as being within the level of ordinary skill in the art. *In re Rose*, 105 USPQ 237 (CCPA 1955).

In addition, applicant has not established any criticality for this claim limitation in stating that "the trunk and branch diameters may be varied according to various performance requirements requiring different distributions of fluid flow" on page 5, paragraph 17 of the specification.

Claims 8 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Swanson et al. in view of Qian and further in view of Swanson* (U.S. PGPub 2002/0128640).

Regarding claim 8, Swanson et al. disclose the ablation catheter of claim 1 in view of Qian. The claim differs from Swanson et al. in calling for the outer cap to be formed of a material comprising a fluoro-polymer. Swanson*, however, discloses a virtual electrode assembly, wherein the outer cap is formed of a material comprising a fluoro-polymer (pg. 5, ¶ 63). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have formed the outer cap of Swanson et al. from a material comprising a fluoro-polymer further in view of the teaching of Swanson* because a fluoro-polymer is an obvious type of plastic that is well-known in the art.

Regarding claim 30, Swanson et al. disclose the virtual ablation electrode of claim 25 in view of Qian. The claim differs from Swanson et al. in calling for the outer cap to be formed of a material comprising a fluoro-polymer. Swanson*, however,

discloses a virtual electrode assembly, wherein the outer cap is formed of a material comprising a fluoro-polymer (pg. 5, ¶ 63). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have formed the outer cap of Swanson et al. from a material comprising a fluoro-polymer further in view of the teaching of Swanson* because a fluoro-polymer is an obvious type of plastic that is well-known in the art.

Claims 25, 28, 30-32, 34, 40, 45-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Swanson‡ et al. (U.S. Pat. No. 6,076,012) in view of Shearon et al. (U.S. Pat. No. 5,919,188).

Regarding claim 25, Swanson‡ et al. disclose a virtual ablation electrode assembly, comprising:

a non-conductive outer cap 430 including a cap inner surface, a cap outer surface and a plurality of pores extending between the cap inner surface and the cap outer surface (col. 36, ln. 11-14 and Fig. 82);

an inner electrode 429 including an interior fluid trunk 432, an exterior surface, and one or more fluid distribution branches 434 extending from the fluid trunk to the exterior surface (col. 35, ln. 32-36 and Fig. 83); and

a fluid chamber formed between the inner electrode 429 and the outer cap 430 (Fig. 83);

wherein, when the electrode is energized and when fluid is delivered through the one or more fluid distribution branches from the trunk, the conductive fluid fills the fluid

chamber and flows out from the chamber through the plurality of pores of the cap establishing ionic transport of ablation energy from the inner electrode to a target site in close proximity to the cap (col. 35, ln. 49-59 and Figs. 82-83).

The claim differs from Swanson‡ et al. in calling for the inner electrode to include one or more spacers protruding from the exterior surface of the inner lumen and contacting the cap inner surface and for the fluid chamber to be maintained by the one more spacers.

Shearon et al., however, teach a virtual electrode assembly, wherein the inner electrode 17 includes one or more spacers 32 protruding from the exterior surface of the inner lumen and contacting the cap inner surface, wherein the spacers maintain the fluid chamber. The spacers of Shearon et al. ensure that the conductive fluid passes out through the outer cap 8 and does not leak back down the shaft proximally (col. 4, ln. 23-25 and Fig. 2).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have the inner electrode of Swanson‡ et al. include one or more spacers to ensure that the conductive fluid passes out through the outer cap and does not leak back down the shaft proximally.

Regarding claim 28, Swanson‡ et al. disclose the virtual ablation electrode of claim 25 in view of Shearon et al. In addition, Swanson‡ et al. disclose the virtual ablation electrode, wherein the outer cap is formed of a material comprising a rigid plastic (col. 36, ln. 22-33).

Regarding claim 30, Swanson‡ et al. disclose the virtual ablation electrode of claim 25 in view of Shearon et al. In addition, Swanson‡ et al. disclose the virtual ablation electrode, wherein the outer cap is formed of a material comprising a fluoro-polymer (col. 36, ln. 22-33).

Regarding claim 31, Swanson‡ et al. disclose the virtual ablation electrode of claim 25 in view of Shearon et al. In addition, Swanson‡ et al. disclose the ablation catheter, wherein the outer cap 22 is formed of a material comprising a rigid plastic (col. 36, ln. 22-33). The claim differs from Swanson‡ et al. in calling for the outer cap to be formed of a material comprising an epoxy resin. It would have been obvious matter of design choice, however, to one of ordinary skill in the art at the time of the invention to have made the outer cap of Swanson‡ et al. to be formed of a material comprising an epoxy resin because applicant has not disclosed that forming the outer cap from an epoxy resin material has any unique criticality or provides an advantage, is used for a particular purpose, or solves a stated problem that is not achieved by a similar material. One of ordinary skill in the art, furthermore, would have expected applicant's invention to perform equally well with either the plastic materials taught by Swanson‡ et al. or the claimed epoxy resin material because both are capable of performing the same functions of being biocompatible and resistant to the high temperatures associated with RF ablation as described in paragraph 16 of the applicant's specification.

Regarding claim 32, Swanson‡ et al. disclose the virtual ablation electrode of claim 25 in view of Shearon et al. In addition, Swanson‡ et al. disclose the virtual ablation electrode, wherein the plurality of pores are arrayed longitudinally along a

length of the outer cap and circumferentially 360 degrees around the outer cap (Fig. 82).

Regarding claim 34, Swanson‡ et al. disclose the virtual ablation electrode of claim 25 in view of Shearon et al. In addition, Swanson‡ et al. disclose the ablation catheter, wherein a maximum diameter of each of the plurality of pores is sized to prevent ingress of blood cells into the fluid chamber from the cap outer surface (col. 36, ln. 17-18).

Regarding claim 40, Swanson‡ et al. disclose the virtual ablation electrode of claim 25 in view of Shearon et al. The claim differs from Swanson‡ et al. in calling for the one or more spacers to extend circumferentially about a proximal end of the electrode. Shearon et al., however, teach the virtual ablation electrode, wherein the one or more spacers 32 extend circumferentially about a proximal end of the electrode (Fig. 2). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have the spacers of Swanson‡ et al. in view of Shearon et al. to extend circumferentially about a proximal end of the electrode also in view of Shearon et al. to ensure that the conductive fluid passes out through the outer cap and does not leak back down the shaft proximally as stated in the preceding rejection of claim 25.

Regarding claim 45, Swanson‡ et al. disclose the virtual ablation electrode of claim 25 in view of Shearon et al. The claim differs from Swanson‡ et al. in calling for the diameter of the fluid trunk of the electrode to be between approximately 0.005 inch and approximately 0.030 inch. It would have been an obvious matter of design choice,

however, to make the diameter of the fluid trunk of the electrode to be between approximately 0.005 inch and approximately 0.030 inch, since such a modification would have involved a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art. *In re Rose*, 105 USPQ 237 (CCPA 1955).

In addition, applicant has not established any criticality for this claim limitation in stating that "the trunk and branch diameters may be varied according to various performance requirements requiring different distributions of fluid flow" on page 5, paragraph 17 of the specification.

Regarding claim 46, Swanson‡ et al. disclose the virtual ablation electrode of claim 25 in view of Shearon et al. The claim differs from Swanson‡ et al. in calling for a diameter of each of the one or more fluid distribution branches to be between approximately 0.005 inch and approximately 0.030 inch. It would have been an obvious matter of design choice, however, to make a diameter of each of the one or more fluid distribution branches to be between approximately 0.005 inch and approximately 0.030 inch, since such a modification would have involved a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art. *In re Rose*, 105 USPQ 237 (CCPA 1955).

In addition, applicant has not established any criticality for this claim limitation in stating that "the trunk and branch diameters may be varied according to various performance requirements requiring different distributions of fluid flow" on page 5, paragraph 17 of the specification.

Claim 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over Swanson‡ et al. in view of Shearon et al. and further in view of Brucker et al. (U.S. Pat. No. 5,643,197).

Regarding claim 29, Swanson‡ et al. disclose the virtual ablation electrode of claim 25 in view of Shearon et al. The claim differs from Swanson‡ et al. in calling for the outer cap to be formed of a material comprising a ceramic. Brucker et al., however, teach an ablation catheter with a porous 6 outer cap 26 for delivering fluid that is made of ceramic (col. 6, ln. 28-33, col. 6, ln. 46-47).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have formed the outer cap of Swanson‡ et al. from a material comprising a ceramic further in view of the teaching of Brucker et al. because ceramic is an obvious type of material for making a porous cap that is known in the art.

Claims 35 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Swanson‡ et al. in view of Shearon et al. and further in view of Swanson et al.

Regarding claim 35, Swanson‡ et al. disclose the virtual ablation electrode of claim 25 in view of Shearon et al. The claim differs from Swanson‡ et al. in calling for the maximum diameter of each of the plurality of pores to be between approximately 0.0005 inch (12.7 μm) and 0.005 inch (127 μm). Swanson et al., however, disclose the virtual ablation electrode, wherein a maximum diameter of each of the plurality of pores is between approximately 0.0005 inch (12.7 μm) and 0.005 inch (127 μm) (col. 8, ln. 34-35). Therefore, it would have been obvious to one of ordinary skill in the art at the time

the invention was made to have made the maximum diameter of each of the plurality of pores of Swanson‡ et al. to be between approximately 0.0005 inch (12.7 μm) and 0.005 inch (127 μm) in view of the teaching of Swanson et al. because it is an obvious alternate pore size to use.

Regarding claim 36, Swanson‡ et al. disclose the virtual electrode of claim 25 in view of Shearon et al. The claim differs from Swanson‡ et al. in calling for the plurality of pores to be formed by a process selected from the group consisting of laser drilling, chemical etching and sintering. Swanson et al., however, disclose the virtual electrode, wherein the plurality of pores is formed by a process selected from the group consisting of laser drilling, chemical etching and sintering (col. 13, ln. 17-20). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have formed the plurality of pores of Swanson‡ et al. by a process selected from the group consisting of laser drilling, chemical etching and sintering in view of the teaching of Swanson et al. because they are obvious methods of forming pores that are known in the art.

Claim 37 is rejected under 35 U.S.C. 103(a) as being unpatentable over Swanson‡ et al. in view of Shearon et al. and further in view of Swanson*.

Regarding claim 37, Swanson‡ et al. disclose the virtual electrode of claim 25 in view of Shearon et al. The claim differs from Swanson‡ et al. in calling for the maximum distance between the exterior surface of the electrode and the cap inner surface to be between approximately 0.003 inch and approximately 0.005 inch. Swanson*, however,

discloses a virtual electrode assembly, wherein the distance between the exterior surface of the electrode and the cap inner surface is 0.005 inch. (pg. 5, ¶ 57). Therefore, it would have been an obvious matter of design choice to make the maximum distance between the exterior surface of the electrode and the cap inner surface of Swanson‡ et al. to be between approximately 0.003 inch and approximately 0.005 inch in view of the teaching of Swanson*, since such a modification would have involved a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art. *In re Rose*, 105 USPQ 237 (CCPA 1955).

Allowable Subject Matter

Claims 2, 4-5, 7, 11, 15, and 27 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alex B. Toy whose telephone number is (571) 272-1953. The examiner can normally be reached on Monday through Friday, 8:00 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C.M. Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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1/24/06

Michael Peffley
MICHAEL PEFFLEY
PRIMARY EXAMINER